UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

MICHAEL ALAN CALTIERI,

by his mother Karen Caltieri,

Individually and on behalf of all others

similarly situated,

Plaintiffs

V.

CIVIL ACTION NO:

PFIZER INC., PHARMACIA & UPJOHN CO.,

Defendants

CIVIL CONSUMER CLASS ACTION COMPLAINT

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ATTORNEYS FOR PLAINTIFF, MICHAEL ALAN CALTIERI by his mother Karen Caltieri, AND THE CONSUMER CLASS

CIVIL CONSUMER CLASS ACTION COMPLAINT

Plaintiff, Michael Alan Caltieri by and through his mother Karen Caltieri, individually, and on behalf of all others similarly situated, by and through his undersigned counsel, brings this Complaint against Defendants Pfizer Inc. ("Pfizer") and its subsidiary Pharmacia & Upjohn Inc. ("Pharmacia") and incorporates by reference thereto the allegations in the related cases of *United States et al. ex rel.Stefan Kruszewski v. Pfizer, Inc.*, Civ. No. 07-4106 (E.D.Pa.) and *United States et al. ex rel.Mark R. Westlock v. Pfizer, Inc.*, Civ. No. 08-CA- 11318 (D.Mass.) (the "Qui Tam Cases") as set forth in the governing False Claims Act Complaint. (attached hereto as Exhibits "A" and "B"), and further allege as follows:

I. NATURE OF THE CASE

- 1. This consumer class action is brought by Michael Alan Caltieri by his mother Karen Caltieri (hereinafter "Plaintiff"), individually and on behalf of a putative nationwide class of similarly situated individuals (the "Class") located throughout Massachusetts and the country for declaratory and injunctive relief and to recover drug payments and overpayments made from at least January 1, 2001 through at least October 31, 2008 (hereinafter, "the relevant time period") as a result of Defendants' unlawful marketing scheme and conspiracy involving the illegal marketing, promotion and sale of the following prescription drugs: Geodon® ("Geodon"), Zyvox® ("Zyvox"), Lyrica® ("Lyrica"), Aricept®, ("Aricept"), Lipitor® ("Lipitor"), Norvasc®, ("Norvasc"), Relpax® ("Relpax"), Viagra®, ("Viagra"), Zithromax® ("Zithromax"), Zoloft® ("Zoloft"), and Zyrtec®, ("Zytec") (collectively referred to as the "Subject Drugs").
- 2. Pfizer sales representatives pushed doctors to prescribe Geodon for such symptoms as anxiety and agitation and for use in children. The FDA had approved Geodon only to treat schizophrenia and bipolar disorder in adults. Pfizer targeted pediatrics and adolescents to

expand off-label use and maintained on its payroll an army of more than 250 child psychiatrists nationwide.

- 3. In 2005, the U.S. Food and Drug Administration warned Pfizer Inc. that its ads touting the antibiotic Zyvox as superior to similar drugs could endanger public health. Pfizer continued to tell doctors that Zyvox worked better than cheaper generic competitors and that it was effective for various types of infections, including those that occur after surgery, even though there was no scientific evidence to support such use.
- Pfizer even promoted Zyvox for use against types of bacteria against which the drug had little or no effect.
- 5. According to a press release by the United States Department of Justice, Pfizer agreed to pay \$2.3 billion to the federal government for illegally promoting Zyvox, the painkiller Bextra, epilepsy and nerve pain drug Lyrica, and the antipsychotic Geodon. ¹
- 6. Pfizer is a repeat offender this is the fourth such settlement of government charges in the last decade. The government said it would monitor the company's conduct for the next five years to rein in the abuses.
- 7. According to Mike Loucks, acting U.S. Attorney for the District of Massachusetts, "Pfizer violated the law over an extensive time period. Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."

 2 Id

http://www.usdoj.gov/opa/pr/2009/September/09-aag-900.html.

- 8. As described more fully in the fee False Claims Act Complaints attached hereto and below, Defendants engaged in the following general types of unfair, deceptive and unlawful acts and omissions as part of their marketing, promotion and sales scheme and conspiracy: (1) they promoted Subject Drugs to physicians by offering, providing and/or paying various types of improper bribes, kickbacks and other illegal remuneration and inducements, whether or not such Subject Drugs were promoted, prescribed and used for indicated/approved medical conditions and in doses and/or for durations that were indicated/approved; (2) they promoted certain Subject Drugs at doses and/or for durations of use that were not medically safe, efficacious, effective or useful, whether or not such Subject Drugs were promoted, prescribed and used for an indicated/approved medical condition; (3) they made false statements and representations about the safety and efficacy of the Subject Drugs; (4) they promoted certain Subject Drugs for non-indicated/unapproved or "off-label" uses.
- 9. In particular, among other things, this Complaint details numerous kickbacks and other types of illegal remuneration and illegal inducements provided by the Defendants to physicians and other healthcare providers to induce them to prescribe the Subject Drugs. For example, the Defendants provided remuneration as inducements to physicians and other healthcare providers to treat patients with certain Subject Drugs. Defendants' illegal course of remuneration and inducements to physicians destroyed the independence of the physician in treating patients like the Plaintiff and others similarly situated.
- 10. The marketing, promotion and sales scheme and conspiracy, in its various forms, as described herein, caused the Plaintiff and members of the Class (and their subrogating insurers) to pay hundreds of millions, if not billions, of dollars for the Subject Drugs. As discussed herein, Pfizer's subsidiary, Pharmacia & Upjohn, has been investigated by and settled

with several governmental agencies regarding this wrongful conduct and admitted, pled guilty to, and was convicted as to certain core aspects of the marketing, promotion and sales scheme and conspiracy with respect to Bextra, a drug not directly at issue in this case.

II. PARTIES

- 5. This action is brought by Plaintiff, Michael Alan Caltieri by his mother Karen Caltieri, individually and on behalf of all other individuals similarly situated. Plaintiff is a minor who was born on July, 7, 1997.
- 6. Plaintiff resides at 144 Lindset Street, Attleboro, Massachusetts, 02703, and who, during the relevant time period, was prescribed and paid for (with his insurance carrier) Geodon, a Subject Drug in this action, for treatment of Attention-deficit/hyperactivity disorder ("ADHD"). At no point was Michael or his mother informed that the treatment he was prescribed was not an FDA approved treatment for ADHD. Put another way, neither Michael nor his mother were ever told that Geodon had not been approved by the FDA for the treatment of his condition. Michael continued to treat with Geodon for about three years. Throughout the course of his treatment, his condition never improved and Michael did not benefit from the treatment at all. He did, however suffer side effects from his treatment with Geodon. At no time during the relevant time period was either Michael or his mother aware of any aspect of any marketing and sales scheme, conspiracy or other illegal conduct averred in this Complaint. Like other members of the Class, Plaintiff suffered damages as a result of the scheme and conspiracy committed by Defendants.
- 7. Defendant Pfizer, Inc., ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, NY. Pfizer merged with Pharmacia in 2002 and, since then, has merged with a number of other pharmaceutical companies, including,

Pharmacia, Upjohn, Searle, and Sugen. On January 26, 2009, Pfizer agreed to buy Wyeth for \$68 billion. Pfizer is the world's largest research-based biomedical and pharmaceutical company and currently ranks number one in pharmaceutical sales in the world with a reported \$48.3 billion in revenue in 2008. Pfizer is a global company principally engaged in the research, manufacture and sale of prescription pharmaceuticals throughout the United States, and the world. At all times relevant hereto, Pfizer engaged or assisted in the manufacture, distribution, sale, promotion and/or marketing of numerous prescription pharmaceuticals. Upon information and belief, Pfizer, at all times relevant hereto, also directed, engaged or assisted in the illegal conduct with respect to the Subject Drugs that are the subject of this Complaint.

- 8. Defendant Pharmacia & Upjohn Co., Inc., ("Pharmacia") is a wholly-owned subsidiary of Pfizer. Pharmacia & Upjohn was created in 1995 by the merger of Upjohn with Pharmacia AB. Pharmacia & Upjohn was later re-created as Pharmacia on April 3, 2000 when Monsanto's Searle Pharmaceuticals division was merged together, prior to merging with Pfizer in 2002. Upon information and belief, Pharmacia, at all times relevant hereto, assisted in directing, engaged or otherwise assisted in the manufacture, distribution, sale, promotion and/or marketing of Pfizer's prescription pharmaceuticals, and specifically in the illegal conduct with respect to the Subject Drugs that are the subject of this Complaint.
- 9. The acts alleged in this Complaint to have been done by each of the defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs.
- 10. Various persons and/or firms, not directly named as defendants herein, including various medical providers and insurers located throughout the country, have participated as co-

conspirators in the violations alleged herein and have performed acts and made statements or omissions in furtherance thereof.

III. JURISDICTION AND VENUE

- 11. This Court has subject matter jurisdiction pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. §§ 1332(a) and 1332(d), because the matter in controversy exceeds \$5 million exclusive of interest and costs, and because more than two-thirds of the members of the putative Class are citizens of states different from that of the Defendants.
- 12. A substantial part of the events or omissions giving rise to the claims in this action occurred in this judicial District and Defendants may be found within this judicial District.

 Venue is proper in this jurisdiction under 28 U.S.C. § 1391. In fact, Ronald Rainero and Mark R. Westlock, who has personal knowledge of the allegations herein, filed a pending Qui Tam Cases against Pfizer on behalf of the federal government in this District.
- 13. Defendants implemented their fraudulent marketing scheme in this District, as well as nationwide, through healthcare providers, sales and other representatives, agents, and others who reside and/or transact business in this District. Defendants' scheme, as alleged herein, thereby affected Class members who reside or transact business throughout the United States, including within this District. Accordingly, Defendants have submitted themselves to the jurisdiction of this Court by committing tortious acts within this State and this judicial District specifically.

IV. FACTUAL ALLEGATIONS

A. The Subject Drugs.

14. The Pfizer Defendants manufacture, market, distribute and sell a number of prescription drugs for treatment of various forms of illnesses. These drugs include, but are not

limited to, Geodon, Lyrica, Zyvox, Aricept, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zytec.

i. Geodon

- 15. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Geodon, a brand name prescription drug generically known as ziprasidone.
- or mixed episodes associated with bipolar disorder. Geodon Intramuscular is indicated for treatment of acute agitation in schizophrenic patients for whom treatment with Geodon is appropriate. Geodon is only FDA approved for adult use and not for use by children. Upon information and belief, despite the limited approved indications for treatment with Geodon, Defendants promoted the drug for, *inter alia*, depression; bipolar maintenance; mood disorder' anxiety; aggression; dementia; attention deficit hyperactivity disorder; obsessive compulsive disorder; autism, posttraumatic stress disorder in unapproved patient populations including pediatric and adolescent patients. Further, upon information and belief, the Defendants promoted Geodon in dosages that were above the maximum approved dosages.
- 17. As stated above, Plaintiff, Michael Caltieri, was prescribed Geodon for the treatment of ADHD during the period of at least 2003 through 2006. Because of Defendants' fraudulent marketing and sales conduct, Plaintiff was prescribed Geodon despite the fact that it is not an FDA approved treatment for ADHD, nor for children, and he was therefore exposed to and actually suffered from a number of the drugs side effects.
- 18. Geodon received a black box warning due to increased mortality in elderly patients with dementia-related psychosis. It also slightly increases the QTC interval in some

patients and increases the risk of a potentially lethal type of heart arrythmia known as torsades de pointes.

- 19. A key component of Pfizer's unlawful marketing with respect to Geodon was that the drug was as safe as or more effective than other antipsychotics and/or more tolerable because of Geodon's comparatively "safe" metabolic profile. However, that marketing of Geodon as comparatively safe and effective was deceptive and misleading and materially minimized and/or concealed Geodon's dangerous side effects. For example, since FDA approval, Pfizer falsely marketed and promoted Geodon as a safer alternative to other antipsychotics including misleading advertisements representing that Geodon has minimal ability to cause neurological side-effects, when in fact it was known to Pfizer that Geodon produced neurological disorders known as Extrapyramidal Symptoms (EPS) in as many as 30% of those that take Geodon at the higher doses.
- Upon information and belief, from January 1, 2001, through December 31, 2007, the exact dates are unknown to Plaintiff and the Class, the Pfizer Defendants illegally promoted Geodon for uses not approved by the FDA and that were not medically-accepted indications for which the U.S. and state Medicaid programs provided coverage; made and disseminated unsubstantiated and false representations about the safety and efficacy of Geodon; and paid kickbacks to health care providers to induce them to prescribe Geodon.

ii. Lyrica

21. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Lyrica, a brand name prescription drug generically known as Pregabalin.

- 22. Lyrica is approved by the FDA for treatment of adjunctive therapy for adults with partial onset seizures; management of post-herpetic neuralgia; management of neuropathuic pain associated with diabetic peripheral neuropathy and for the treatment of fibromyalgia. Upon information and belief, despite the limited approved indications for treatment with Lyrica, Defendants promoted the drug for, *inter alia*, chronic pain; neuropathic pain; perioperative pain and to treat migraines.
- Common side effects of Lyrica include mild-to-moderate dizziness, sleepiness,
 blurred vision, dry mouth, swelling of the hands and feet and weight gain.
- 24. Accordingly, upon information and belief, from September 1, 2005, through October 31, 2008, the exact dates are unknown to Plaintiff and the Class, the Pfizer Defendants illegally promoted Lyrica, for uses not approved by the FDA and that were not medically-accepted indications for which the U.S. and state Medicaid programs provided coverage; made and disseminated unsubstantiated and false representations about the safety and efficacy of Lyrica; and paid kickbacks to health care providers to induce them to prescribe Lyrica.

iii. Zyvox

- 25. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Zyvox, a brand name prescription drug generically known as linezolid.
- 26. Zyvox is approved by the FDA for treatment of vancomycin-resistant Enterococcus faecium infections; nosocomial pneumonia; community-acquired pneumonia and complicated skin and skin structure infections, including diabetic foot infections without concomitant osteomyelitis. Upon information and belief, despite the limited approved indications for treatment with Zyvox, Defendants promoted the drug for, inter alia, infections

caused by methicillin-resistant *Staphylococcus aureus* ("MRSA") generally, rather than only those types for which Zyvox was FDA-approved.

- 27. Common side effects of short-term use of Zyvox include headache, diarrhea, and nausea. However, the side effects become more serious when Zyvox is used for longer duration, and include bone marrow suppression and low platelet counts, particularly when used for more than two weeks. Zyvox may also cause peripheral neuropathy, optic nerve damage and lactic acidosis.
- Upon information and belief, from September 1, 2005, through October 31, 2008, the exact dates are unknown to Plaintiff and the Class, the Pfizer Defendants illegally promoted Zyvox for uses not approved by the FDA and that were not medically-accepted indications for which the U.S. and state Medicaid programs provided coverage; made and disseminated unsubstantiated and false representations about the safety and efficacy of Zyvox; and paid kickbacks to health care providers to induce them to prescribe Zyvox.

iv. Aricept

- 29. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Aricept, a brand name prescription drug generically known as donepezil.
- 30. Aricept was approved by the FDA in November 1996 for the symptomatic treatment of mild to moderate Alzheimer's disease. In 2006, Aricept was approved for the treatment of severe Alzheimer's disease, becoming the first and only prescription to treat the full spectrum of Alzheimer's disease.
- 31. Common side effects of Aricept include fainting, nausea, vomiting, diarrhea, bruising, sleep deprivation, muscle cramps, loss of appetite and tiredness.

32. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Aricept.

v. Lipitor

- 33. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Lipitor, a brand name prescription drug generically known as atorvastatin.
- 34. Lipitor was approved by the FDA in December 1996 to reduce elevated LDL-cholesterol. In 2007, the FDA approved Lipitor to be used as treatment to aid the prevention of nonfatal heart attacks, as well as fatal and nonfatal strokes.
- 35. Common side effects of Lipitor include headache, constipation, diarrhea, gas, upset stomach and stomach pain, rash and muscle and joint pain. Lipitor can also cause serious side effects, including serious muscle problems that can lead to kidney problems or kidney failure and liver problems.
- 36. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Lipitor.

vi. Norvasc

37. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Norvasc, a brand name prescription drug generically known as amlodipine.

- 38. Norvasc was approved by the FDA in July 1992 to treat high blood pressure and angina.
- 39. Common side effects of Norvasc include feet or ankle swelling, tiredness, headache and dizziness.
- 40. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Norvasc.

vii. Relpax

- 41. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Relpax, a brand name prescription drug generically known as eletriptan.
- 42. Relpax was approved by the FDA in December 2002 for the acute treatment of migraine headaches, with or without aura, in adults.
- 43. Common side effects of Relpax include dizziness, nausea, weakness, feeling sleepy, and pain or pressure sensation in chest or throat.
- 44. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Relpax.

viii. Viagra

- 45. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Viagra, a brand name prescription drug generically known as sildenafil.
 - Viagra was approved by the FDA in 1998 to treat erectile dysfunction.
- 47. Common side effects of Viagra include headache, facial flushing, upset stomach, bluish vision, blurred vision and sensitivity to light.
- 48. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Viagra.

.ix. Zithromax

- 49. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Zithromax, a brand name prescription drug generically known as azithromycin.
- 50. Zithromax was approved by the FDA in 1992 for adults to treat infections caused by bacteria, such as respiratory infections, skin infections, and ear infections. In 1995, Zithromax was approved for use in children.
- 51. Common side effects of Zithromax include diarrhea, nausea, abdominal pain, and vomiting.
- 52. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash,

travel, and meals to health care professionals to induce them to promote and prescribe Zithromax.

x. Zoloft

- 53. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Zoloft, a brand name prescription drug generically known as sertraline.
- 54. Zoloft was approved by the FDA in 1991 for the treatment of depression. In February 2003, Zoloft was approved by the FDA for acute and long-term treatment of social anxiety disorder.
- Common side effects of Zoloft include dry mouth, insomnia, sexual side effects,
 diarrhea, nausea and sleepiness.
- 56. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Zoloft.

xi. Zyrtec

- 57. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Zyrtec, a brand name prescription drug generically known as cetirizine.
- 58. Zyrtec was approved by the FDA in 1996 for the treatment of allergies, hay fever, angioedema and urticaria.
- Common side effects of Zyrtec include drowsiness, dry mouth, stomach pain, tiredness and trouble sleeping.

- 60. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Zyrtec.
 - B. <u>Defendants' Conspiracy to Induce Prescriptions of Subject Drugs by Offering Improper Remuneration to Physicians.</u>
- And conspiracy with healthcare providers and others which was intended to induce, and did induce, providers to prescribe Subject Drugs to patients, despite the availability of less expensive, approved, alternative courses of treatment. Following are examples of practices used by the Pfizer Defendants which were intended to encourage, and did encourage, healthcare providers to prescribe Subject Drugs over less expensive, approved, alternative courses of treatment. On information and belief, Plaintiff's healthcare provider was influenced by, and prescribed Geodon to Plaintiff and the Class Members as a result of, one or more of these practices.

i. Phony Speaker Fees paid for by "Honorariums."

62. Upon information and belief, the Pfizer Defendants' sales representatives paid "honorarium" fees to physicians, ostensibly as compensation to physicians for agreeing to speak at a formal function, such as a dinner. However, in most instances, the lectures were promotional in nature for off-label uses of the Subject Drugs. Upon information and belief, honorariums were sometimes provided as cash, or as reimbursement for travel, or for some other improper cost.

ii. Phony Preceptorships.

63. Upon information and belief, the Pfizer Defendants' "preceptorship" programs were ostensibly a teaching session in which a sales representative's physician (in his or her area) would agree to teach the sales representatives certain technical aspects of his or her practice in exchange for a sum of money. In numerous ways, these "preceptorships" lacked the characteristics of legitimate preceptorships and often were used as kickbacks by sales representatives as a means of improperly providing cash to the physicians.

iii. Other Inducements

- 64. Upon information and belief, the Pfizer Defendants have also provided and/or arranged for many other financial and other forms of inducements to stimulate sales of the Subject Drugs at the expense of Plaintiff and the Class. Such inducements included, but were not limited to, the provision of gifts in the form of cash, entertainment, travel and meals. Further, the Pfizer Defendants distributed misleading literature regarding the safety and efficacy of the Subject Drugs, promoted CME and other purported educational lectures that were in fact promotional in nature for off-label uses of the Subject Drugs, funded scientific studies that misrepresented the evidence supporting the safety of the Subject Drugs, funded roundtable discussions, promotional advertisement, journal supplements and Pfizer sponsorship of physician meetings and provided Pfizer-prepared and funded promotional materials to be used by physicians that were paid to promote the Subject Drugs.
 - C. The Federal Government's Investigation of the Pfizer Defendants, Prosecution, Criminal Conviction and Settlement of the Charges and Investigation, and Admission, Acceptance and/or Other Manifestations of Certain Core Conduct by the Pfizer Defendants.
- 65. On September 2, 2009, the Department of Justice ("DOJ") announced that the largest health care fraud settlement in its history was reached with Defendants Pfizer and Pharmacia. Pfizer and its subsidiary Pharmacia & Upjohn Co., Inc., agreed to pay \$2.3 billion to

resolve criminal and civil liability arising from the illegal promotion of the Subject drugs, as well as another drug, Bextra. The investigation was triggered by the filing of several Whistleblower lawsuits filed under the *qui tam* provisions of the False Claims Act that are pending in the District of Massachusetts, the Eastern District of Pennsylvania, and the Eastern District of Kentucky, whose prosecution and litigation was handled by the U.S. Attorney's offices for those Districts as well as the Civil Division of the Department of Justice.

- 66. The Settlement resolved past off-label promotional practices related to Bextra, a drug that is not directly at issue in this Complaint, as well other DOJ investigations involving alleged off-label promotional practices concerning Lyrica, Zyvox, and Geodon, and as allegations related to certain improper payments and other inducements to healthcare professionals involving those drugs and other additional Subject Drugs. The Settlement also resolved the aforementioned *qui tam* cases.
- 67. Further, it was announced that the Pfizer had reached agreements with attorneys general in 42 states and the District of Columbia, to settle state civil consumer protection allegations related to its promotional practices regarding Geodon. As a condition of that settlement, Pfizer will pay a total of \$33 million to the settling states.
- 68. The agreement provides a combined federal and state civil settlement of \$1billion related to the Subject Drugs. The Company also will pay \$1.3billion in criminal penalties related only to Bextra, a drug that is not at issue in this Complaint. As part of the criminal resolution related to Bextra Defendant Pharmacia & Upjohn has agreed to plead guilty to one count of felony misbranding under 21 U.S.C. §§331(a), 33(a) and 352.
- 69. Aside from the criminal component of the announced settlement, the terms of the Settlement require Pfizer to make payments to resolve the civil allegations involving past

promotional practices with respect to Lyrica in the amount of \$50 million. Likewise, Pfizer has agreed to pay \$301 million to resolve civil allegations regarding Geodon and \$98 million to resolve civil allegations regarding Zyvox. Pfizer acknowledges certain improper actions related to the promotion of Zyvox.

- 70. The civil settlement resolves allegations that Pfizer violated the federal False Claims Act by illegally promoting Geodon, Zyvox and Lyrica, as well as Bextra, a drug not directly at issue in this Complaint, for uses not approved by the FDA and that were not medically-accepted indications for which the U.S. and state Medicaid programs provided coverage; making and disseminating unsubstantiated and false representations about the safety and efficacy of those drugs; and paying kickbacks to health care providers to induce them to prescribe those drugs. The settlement also resolves allegations that Pfizer was paying kickbacks to health care providers in connection with its marketing of nine other drugs, including the Subject Drugs Aricept, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft and Zyrtec.
- 71. The averments of the Information are incorporated by reference in this Complaint as if fully set forth herein. The averments of the Information, which Defendant Pharmacia has admitted and fully accepted as part of its guilty plea and conviction, and as part of the Pharmacia Defendants' settlement of the government's investigation, comprise certain core aspects of the fraudulent marketing, promotion and sales scheme and conspiracy alleged by Plaintiff against the Pfizer Defendants, and others, herein.
- Also as part of the settlement to resolve the federal government's charges and the civil liabilities, Defendant Pfizer has entered into a comprehensive five-year Corporate Integrity Agreement ("CIA") with the HHS-OIG. The CIA requires enhanced accountability, increased transparency and wide-ranging monitoring activites conducted by both internal and independent

external reviewers. The CIA also requires that an Audit Committee of Pfizer's Board of Directors annually review the company's compliance program and certify as to its effectiveness; and also that senior executives annually certify about compliance with the requirement that Pfizer notify doctors about the global settlement and establish a mechanism doctors can use to report questionable conduct by a Pfizer representative and that the company post on its web site information about payments to doctors, such as honoria, travel or lodging.

- 73. The Plaintiff and the Class have filed this action because the agreement to resolve the federal government's investigation against the Pfizer Defendants will not compensate the Plaintiff and the Class for all of the damages they have suffered and all of the damages to which they are entitled under all applicable laws.
- 74. Indeed, the civil Qui Tam cases pending in the Districts of Massachusetts, the Eastern District of Pennsylvania and the Eastern District of Kentucky, which upon information and belief seek broad relief for the federal government's losses incurred as to the Subject Drugs as a result of Defendants' fraudulent scheme and conspiracy will not compensate Plaintiff and the Class for their injury and damages.

V. FRAUDULENT CONCEALMENT AND TOLLING OF LIMITATIONS PERIOD

- 75. The Pfizer Defendants have concealed from the public the details of their underlying fraudulent and other illegal conduct not only during the time that they engaged in that conduct so as to avoid detection and cessation of their ill-gotten profits, but even to this day to avoid public scrutiny, any concomitant negative perception of their business, and liabilities to Plaintiff and members of the Class resulting from civil litigation.
- 76. Plaintiff had no knowledge of any of fraud or fraudulent schemes, illegal sales and marketing programs and conduct, kickbacks, bribery, payments or provision of illegal

remuneration, conspiracies and concerted activities, illegal promotional activities, or other unlawful conduct alleged herein with respect to the Subject Drugs, or of any facts that might have led to the discovery thereof in the exercise of reasonable diligence, until the earliest date of September 2, 2009 when the above mentioned Settlement was announced and when the federal government filed its criminal Information and the DOJ issued its Press Release reporting on the resolution of the several criminal and civil allegations.

- 77. Plaintiff could not have discovered the unlawful conduct alleged herein at an earlier date by the exercise of due diligence because of the deceptive practices and techniques of secrecy employed by all of the Defendants and their co-conspirators to avoid detection of, and to conceal, their unlawful conduct and conspiracies.
- 78. By reason of the foregoing, the claims of Plaintiff and members of the Class are timely under any applicable statute of limitations (as tolled by the filing of this Class Action Complaint) pursuant to the discovery rule and the doctrine of fraudulent concealment.
- 79. The Defendants have been aware of their unlawful conduct and conspiracies since the inception of such conduct. To this day, however, despite Defendants' awareness of their unlawful conduct, their knowledge of the federal investigation of relevant conduct and now their resolution of the charges by the United States of America, the Defendants continue to conceal from the public, including Plaintiff and the Class, the full details of their unlawful conduct.
- 80. The Defendants' failure to properly disclose their unlawful conduct and conspiracies, and other acts and omissions as alleged herein, was and is willful, wanton, malicious, outrageous, and was and continues to be undertaken in deliberate disregard of, or with reckless indifference to, the rights and interests of Plaintiff and members of the Class.

VI. CLASS ACTION ALLEGATIONS

81. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, Plaintiff brings this action on behalf of herself and a Class, defined as follows:

All individuals in the United States and its territories who, for purposes other than resale, purchased, Geodon, Zyvox, Lyrica, Aricept, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zytec from at least January 1, 2001 through at least October 31, 2008.

Excluded from the Class are (a) Defendants and any entities in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors and (b) any co-conspirators (including, among other, insurers with whom Defendants directly negotiated about aspects of the fraudulent scheme and conspiracy). Also excluded from the Class are any judges or justices to whom this action is assigned, together with any relative of such judge(s) or justice(s) within the third degree of relationship, and the spouse of any such person.

82. Plaintiff contends that this suit is properly maintainable as a class action pursuant to Rules 23 (b)(1), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure.

NUMEROSITY

83. The Class consists of numerous individuals and entities throughout the United States, making individual joinder impractical, in satisfaction of Rule 23(a)(1). Plaintiff is unable to provide an approximation of the number of potential class members, but notes that the dollar sales amount of the Pfizer Defendants was in the hundreds of millions. The disposition of the claims of the Class members in a single class action will provide substantial benefits to all parties and to the Court

TYPICALITY

84. The claims of the representative Plaintiff are typical of the claims of the Class, as required by Rule 23(a)(3), in that Plaintiff, like all Class members, purchased Defendants' Subject Drugs. Like all Class Members, Plaintiff was damaged by Defendants' misconduct, in that, among other things, they purchased Subject Drugs to treat a condition while Defendants were actively engaged in their fraudulent marketing, promotion and sales scheme and conspiracy.

COMMON QUESTIONS OF LAW AND FACT

- 85. The factual and legal bases of Defendants' fraudulent marketing, promotion and sales scheme and conspiracy are common to all members of the Class and represent a common thread of misconduct resulting in injury to Plaintiff and all members of the Class.
- 86. Questions of law and fact common to Plaintiff the Class abound in this case, and those questions predominate over any questions affecting individual Class members, within the meaning of Rule 23(a)(2) and (b)(3). These common questions of law and fact include, but are not limited to, the following:
 - (a) Whether Defendants engaged in the fraudulent marketing, promotion and sales scheme and conspiracy alleged herein;
 - (b) Whether the conspiracy was implemented;
 - (c) Whether Defendants used kickbacks, bribes and/or other payments or provision of illegal remuneration or inducements to induce physicians and other healthcare providers to prescribe, administer, or otherwise treat patients with any of the Subject Drugs, whether or not such prescribing, administration or treatment was for medical conditions that were FDAapproved;
 - (d) Whether Defendants engaged in a fraudulent and/or unfair and deceptive scheme of improperly marketing, promoting and selling any of the Subject Drugs for durations of use or in dosages that exceeded or were otherwise outside the scope of FDA approval or that were not medically safe, efficacious, effective or useful;

- (e) Whether Defendants coached or instructed physicians or others on how to conceal the off-label nature of the Subject Drugs on claim forms submitted by or to patients and members of the Class or the federal government;
- (f) Whether Defendants prepared, funded and published studies and other materials which contained false information and misrepresentations concerning the safety and efficacy of the Subject Drugs;
- (g) Whether Defendants prepared, funded and published studies and other materials which contained false information regarding off-label uses, or the validity of or propriety of or scientific and other support for, off-label uses of the Subject Drugs;
- (h) Whether, and on how many occasions, Defendants provided false information and made false statements to the federal government regarding their sales and marketing scheme pertaining to the Subject Drugs;
- (i) Whether Defendants utilized others and/or engaged in conspiracies to assist in the publication and dissemination of false statements, or fraudulent studies, to physicians concerning the safety and efficacy of the Subject Drugs;
- (j) Whether Defendants engaged in a pattern and practice with the intent of deceiving and defrauding Plaintiff and the Class and with the intent of suppressing the unlawful conduct and conspiracy;
- (k) Whether Defendants violated Massachusetts's or any other state's consumer protection statute;
- Whether Defendants are liable under state conspiracy and/or state concert of action and/or state aiding and abetting/facilitating laws;
- (m) Whether Defendants unjustly enriched themselves at the expense of Plaintiff and members of the Class;
- (n) Whether Defendants' illegal bribes, kickbacks, payments of illegal remuneration and/or other illegal inducements provided to physicians and other medical providers directly and proximately caused Plaintiff and members of the Class to pay for any of the Subject Drugs, or to pay more for the Subject Drugs than they otherwise would have paid either for those specific Subject Drugs or for an alternative drug or treatment which was more efficacious;
- (o) Whether Plaintiff and the Class are entitled to compensatory damages, and, if so, the nature of such damages;

- (p) Whether Plaintiff and members of the Class are entitled to punitive damages, treble damages or exemplary damages and, if so, the nature of such damages;
- (q) Whether Plaintiff and members of the Class are entitled equitable relief pursuant to their claim for unjust enrichment or otherwise; and
- (r) Whether Plaintiff and members of the Class are entitled to an award of reasonable attorneys' fees, prejudgment interest, post-judgment interest and costs of suit.

<u>ADEQUACY</u>

87. Plaintiff, Michael Alan Caltieri by and through his mother Karen Caltieri, will fairly and adequately represent and protect the interests of the Class, as required by Rule 23(a)(4). Plaintiff has retained counsel with substantial experience and expertise in the prosecution of both statewide and nationwide class actions. Plaintiff and his counsel are committed to the vigorous prosecution of this action on behalf of the Class and have the financial resources to do so. Neither Plaintiff nor counsel have any interests adverse to those of the Class.

SUPERIORITY

- 88. A class action is superior to other available methods for the fair and efficient adjudication of the controversy under Rule 23(b)(3). Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves resources of the courts and the litigants, and promotes consistency and efficiency of adjudication.
- 89. The prosecution of separate actions by or against individual members of the plaintiff Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class. These adjudications would establish incompatible standards of

conduct for the Defendants which would, as a practical matter, be dispositive of the interests of the other class members not parties to the adjudications or would substantially impair or impede their ability to protect their interests.

90. Defendants also have acted or refused to act on grounds generally applicable to all members of the Class, thereby making appropriate declaratory and injunctive relief with respect to the Class as a whole.

VII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF Violation of Massachusetts General Law Ch. 93A, et seq.

- 91. Plaintiff incorporates by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.
- 92. Plaintiff and the Class are consumers who purchased Subject Drugs for personal use. Massachusetts has enacted laws to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising. Massachusetts allows consumers a private right of action under such laws.
- 93. By the misrepresentations and non-disclosure of material facts alleged above, the Defendants deceived and continue to deceive consumers, such as Plaintiff and the Class. This conduct constitutes unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce within the meaning of Massachusetts General Law Ch. 93A, et seq., and warrants the application of the laws of Massachusetts to all Defendants in this Court.
- 94. As part of their guilty plea and payment of fines and money for civil liabilities, Defendants Pfizer and Pharmacia agreed to pay substantial sums of money to the states, including Massachusetts. Such admission of liability and payment of civil liabilities to the states warrants the application of the laws of Massachusetts to all Defendants in this Court.

- 95. The misrepresentation and non-disclosure of material facts by the Defendants caused the Plaintiff and the Class to suffer losses within the meaning of Massachusetts General Law Ch. 93A, et seq.
- 96. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including Massachusetts, Plaintiff and the Class have and will continue to suffer damages in an amount to be determined at trial.
- 97. On September 4, 2009, plaintiff sent a demand letter pursuant to Mass. Gen. Laws Ch. 93A § 9(3) to: Defendants.

WHEREFORE, Plaintiff, Michael Caltieri by and through his mother Karen Caltieri, on behalf of himself and the members of the Class, respectfully seek the relief set forth below.

SECOND CLAIM FOR RELIEF Violation of Consumer Protection Statutes of the Remaining 49 States, District of Columbia and Puerto Rico

- 98. Plaintiff incorporates by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.
- 99. Plaintiff and the Class are individual consumers who purchased Subject Drugs for their own personal use or for the personal use of those on whose behalf they have purchased the Subject Drugs. All 49 of the remaining states, the District of Columbia and Puerto Rico have enacted statutes to protect consumers against unfair, unconscionable, deceptive or fraudulent business practices, unfair competition and false advertising. Most states allow consumers a private right of action under these statutes.
- 100. By the actions and failures to act of Defendants, including the above-described false and misleading representations, marketing schemes, kickbacks, bribes, payments and provision of illegal remuneration and inducements, omissions, concealment, and non-disclosure

of material facts as alleged above, the Defendants deceived, and continue to conceal their deception of, consumers such as Plaintiff and members of the Class. This conduct constitutes unlawful, unfair, unconscionable, deceptive and fraudulent business practices within the meaning of consumer protection statutes of the remaining 46 states, the District of Columbia and Puerto Rico.

- damages by, as described above, paying or otherwise providing to physicians and other health care providers kickbacks and bribes as inducements for them to prescribe, administer, or otherwise treat patients with the Subject Drugs that are the subject of this action, whether for offlabel uses or otherwise. Such conduct was directed to and induced physicians and other healthcare providers, and affected their patients and other consumers, including Plaintiff and members of the Class, who paid for the Subject Drugs, throughout the remaining 49 states, the District of Columbia and Puerto Rico. Such conduct is actionable under the consumer protection statutes of these jurisdictions. As a direct and proximate result of Defendants' conduct, Plaintiff and the Class have suffered damages in an amount to be determined at trial, and are entitled to compensatory damages, treble damages, attorneys' fees and costs of suit, and any other damages provided under these statues.
- 102. Additionally, in prescribing, administering or otherwise treating patients with the Subject Drugs, physicians relied upon Defendants' above-described misrepresentations, omissions, non-disclosures and concealment of material facts, and other fraudulent conduct regarding the safety and efficacy of the Subject Drugs. Such conduct was directed to, and acted upon by, physicians and healthcare providers, and affected their patients and other consumers, including members of the Class who paid for the Subject Drugs, throughout the remaining 49

states, the District of Columbia and Puerto Rico. Such conduct is actionable under the consumer protection statutes of these states, districts and territories. As a direct and proximate result of this conduct of Defendants, members of the Class have suffered damages in an amount to be determined at trial, and are entitled to compensatory damages, treble damages, attorneys' fees and costs of suit, and any other damages provided by these statutes.

WHEREFORE, Plaintiff, Michael Caltieri by and through his mother Karen Caltieri, on behalf of himself and the members of the Class, respectfully seek the relief set forth below.

THIRD CLAIM FOR RELIEF Conspiracy/Concert of Action

- 102. Plaintiff incorporates by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.
- Plaintiff and the Class, and continuing thereafter through at least February October 31, 2008, Defendants acted in concert with one another, with physicians and healthcare providers and with other co-conspirators as described above, in a continuing conspiracy and/or concerted action to violate federal and state laws and to defraud Plaintiff and the Class by causing Plaintiff and the Class to purchase these Subject Drugs that had been prescribed to them due to kickbacks, bribes and payment or provision of illegal remuneration or other inducements. In the absence of Defendants' conspiracy, Plaintiff and the Class would not have been prescribed these Subject Drugs and would not have been exposed to/and suffered from their related side effects. Further, in the absence of this conspiracy and/or concerted action, Plaintiff and the Class would not have purchased these Subject Drugs or would have paid much less for them or for other drugs or alternative treatments which would have been more beneficial in treating their conditions.

- Defendants and their co-conspirators, as described above, engaged in this conspiracy and/or concerted action to defraud by causing the Class to purchase these Subject Drugs for off-label uses that were not approved by the FDA and were not scientifically proven to be safe, efficacious, effective or useful for the conditions for which such Subject Drugs were prescribed, administered or otherwise provided and for which members of the Class made payments. Defendants did so by explicitly making and/or disseminating unsubstantiated and/or false representations or statements about the safety and efficacy of the Subject Drugs. In the absence of Defendants' conspiracy and/or concerted action, the Class would not have paid for these drugs at all and/or would have paid much less for them or for other drugs or alternative treatments which would have been more beneficial in treating their conditions.
- 105. As detailed above and in the documents incorporated by reference relating to the criminal investigation and charges brought against the Pfizer Defendants, those Defendants have agreed to resolve the federal government's charge of violating Title 21, United States Code, §§ 331(a), 333(a)(2) and 352.
- and their co-conspirators engaged in a wide range of activities the purpose and effect of which was to defraud the Plaintiff and the Class. These activities have been set forth in great detail above and throughout this Complaint, and have been incorporated by reference herein, including, but not limited to, the following activities:
- (a) Defendants discussed and agreed among themselves and with their coconspirators to offer, provide and accept kickbacks and bribes in exchange for the improper sales of these Subject Drugs for both indicated and off-label uses, thereby resulting in the Defendants

obtaining additional revenues and profits from their fraudulent sales and marketing scheme regarding these Subject Drugs for off-label uses as well as their fraudulent sales and marketing scheme regarding these Subject Drugs for indicated uses.; and

- (b) Defendants discussed and agreed among themselves and with their coconspirators to create the above-alleged fraudulent scheme to carry out their common purpose and goal of deriving huge profits from their fraudulent sales and marketing scheme regarding these Subject Drugs for off-label uses as well as their fraudulent sales and marketing scheme regarding these Subject Drugs for indicated uses.
- another, with physicians and healthcare providers and with other co-conspirators throughout the country, to commit the conduct and scheme described herein to defraud Plaintiff and the Class, and acted pursuant to a common design or plan with respect to the fraudulent scheme and conspiracy. As described in this Complaint, Defendants gave substantial assistance or encouragement to each other, to physicians and healthcare providers, and to other co-conspirators throughout the country in furtherance and as part of the fraudulent scheme and conspiracy in order to defraud Plaintiff and the Class.
- 108. Defendants' conspiracy and concerted actions have directly and proximately caused the Plaintiff's and the Class members' damages. As a direct and proximate result of Defendants' conspiracies and/or concerted actions perpetrated upon Plaintiff and the Class, Defendants are jointly and severally liable to Plaintiff and the Class for all damages Plaintiff and the Class have sustained, plus exemplary damages and, punitive damages, as well as the cost of suit and reasonable attorneys' fees.

WHEREFORE, Plaintiff, Michael Caltieri by and through his mother Karen Caltieri, on behalf of himself and the members of the Class, respectfully seek the relief set forth below.

FOURTH CLAIM FOR RELIEF Unjust Enrichment

- 109. Plaintiff, Michael Caltieri by and through his mother Karen Caltieri, incorporates by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.
- 110. By engaging in the conduct described in this Complaint, Defendants have knowingly obtained benefits from Plaintiff and the Class under circumstances such that it would be inequitable and unjust for these Defendants to retain them.
- 111. Defendants have collected payments for these Subject Drugs from Plaintiff and the members of the Class that vastly exceeded the payments to which Defendants were entitled as a matter of law. In exchange for these payments, and at the time they made these payments, Plaintiff and members of the Class expected that their physicians were not prescribing these Subject Drugs due to Defendants' kickbacks, bribes or payment or provision of illegal remuneration or other illegal inducements; that these Subject Drugs were safe, medically efficacious, effective and useful for the particular conditions or symptoms for which they were prescribed; and/or that these Subject Drugs, in instances where these Subject Drugs were provided for FDA-approved conditions, were also being provided and administered in doses and over durations that were FDA-approved. Plaintiff and the Class would not have paid what they did for these Subject Drugs in the absence of Defendants' wrongful conduct.
- 112. Thus, Defendants will be unjustly enriched if they are permitted to retain the full amounts paid to them by Plaintiff and the members of the Class.

- 113. Plaintiff and the members of the Class are therefore entitled to an award of compensatory and punitive damages in an amount to be determined at trial or to the imposition of a constructive trust upon the wrongful profits obtained by, revenues obtained by, and benefits conferred upon Defendants as a result of their wrongdoing and the purchases made by Plaintiff, and members of the Class.
- 114. Plaintiff and the members of the Class have no remedy at law to prevent Defendants from continuing the inequitable conduct alleged herein and the continued unjust retention of the payments made to Defendants on behalf of Plaintiff and members of the Class.

WHEREFORE, Plaintiff, Michael Caltieri by and through his mother Karen Caltieri, on behalf of himself and the members of the Class, respectfully seek the relief set forth below.

DEMAND FOR RELIEF

WHEREFORE, Plaintiff, Michael Caltieri by and through his mother Karen Caltieri, and the Class demand judgment against Defendants in each claim for relief, jointly and severally, and as follows:

- (a) On the claim under the consumer protection statutes of Massachusetts and the 49 remaining states, the District of Columbia and Puerto Rico, compensatory damages, treble damages, punitive damages, and any other damages permitted under such statutes, such amounts to be determined at trial, plus Plaintiff's costs in this suit and reasonable attorneys' fees;
- (b) On the conspiracy/concert of action claim, compensatory damages, treble damages and punitive damages, such amounts to be determined at trial, plus Plaintiff's costs in this suit and reasonable attorneys' fees;
- (c) On the claim for unjust enrichment, recovery in the amount of paid on behalf of Plaintiff, and the Class' (i) payments for these Subject Drugs to treat conditions for

which these drugs were not approved by the FDA; (ii) over-payments for these Subject Drugs resulting from Defendant-promoted treatment with excessive dosages or over excessive durations that were not FDA-approved, even if the underlying medical conditions for use were FDA-approved; (iii) payments or over-payments for these Subject Drugs where Plaintiff's and the Class' purchases arose from bribes, kickbacks, illegal remuneration or other illegal inducements paid or provided to their physicians by the Defendants, and (iv) payments for these Subject Drugs to treat conditions for which the Subject Drugs were not effective and for which Defendants made and/or disseminated unsubstantiated and false representations about the safety and efficacy of the Subject Drugs that induced providers to prescribe the Subject Drugs for those conditions in such amounts to be determined at trial, plus Plaintiff's costs in this suit and reasonable attorneys' fees;

- (d) Awarding Plaintiff and the Class other appropriate equitable relief, including, but not limited to, disgorgement of all profits obtained from their wrongful conduct and declaratory and injunctive relief;
- (e) Awarding Plaintiff and the Class pre-judgment and post-judgment interest at the maximum rate allowed by law;
- (f) Awarding Plaintiff and the Class their costs and expenses in this litigation, including expert fees, and reasonable attorneys' fees; and
- (g) Awarding Plaintiff and the Class such other and further this relief as may be just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury on all issues so triable.

Dated: September 4, 2009

Respectfully submitted,

Ronald J. Ranta, Esquire

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